

REMARKS

This Amendment rewrites claims 18, 30 and 31. The asymmetric coating layers feature of these claims is supported by page 8, lines 14-27 and Fig. 2. Claims 18-34 are pending.

This Amendment overcomes the 35 U.S.C. § 102(b) rejection of claims 18, 19, 21, 22 and 24-32 over U.S. Patent No. 5,820,917 to Tuch. A feature of the claimed material for medical use, device, and method for preparation of a multilayered material for medical use is the presence of asymmetric coating layers wherein different layers cover different portions of a core material, different layers comprise different biologically active agents, or both.

Tuch fails to disclose the asymmetric coating layers feature of the claimed invention. Reconsideration and withdrawal of the anticipation rejection of claims 18, 19, 21, 22 and 24-32 over Tuch are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 20 and 23 over Tuch in combination with U.S. Patent No. 5,830,480 to Ducheyene et al. is respectfully traversed. As discussed above, a feature of the claimed material, device and method for preparation of a multilayer material for medical use is the presence or formation of asymmetric coating layers wherein different layers cover different portions of

the core material, different layers comprise different biologically active agents, or both. The inventors have discovered that it is possible to tailor a material for medical use in humans or animals such that it can serve multiple purposes or react differently depending upon its location within the human or animal body, by creating asymmetric layers having different compositions, different layers at different locations, or both (Specification, page 8, lines 14-27).

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed material, device and method for preparation of a multilayered material because the cited references fail to disclose or suggest this asymmetric coating layer feature. Tuch does not disclose or suggest the use of two different biologically active agents.

The deficiencies of Tuch are not remedied by the additional disclosure of Ducheyne et al., which also fails to disclose or suggest multiple, asymmetric coating layers over its sol-gel produced particles. Reconsideration and withdrawal of the obviousness rejection of claims 20 and 23 over Tuch in combination with Ducheyne et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 33 and 34 over Tuch in combination with U.S. Patent No. 6,013,855 to McPherson et al. is also traversed. As discussed above, a feature of the claimed material, device and method for preparation of a multilayered material is the presence of asymmetric layers of coating material such that different layers cover different portions of the core material, different layers comprise different biologically active agents, or both. The presence of the asymmetric coating layers permits tailoring of the material and a medical device prepared from the material for specific purposes such as prolonged release of biologically active agents and/or release at different stages of the life cycle of the device.

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed method because neither reference discloses or suggests the formation of asymmetric coating layers. The deficiencies of Tuch, discussed above, are not remedied by the additional disclosure of McPherson et al., which is cited to show grafting of polymers upon medical devices, and fails to disclose or suggest the asymmetric coating layer feature of the claimed method. Reconsideration and withdrawal of the obviousness

U.S. Appln. S.N. 10/069,785  
AMENDMENT

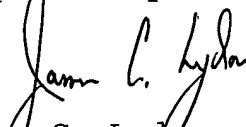
**PATENT**

rejection of claims 33 and 34 over Tuch in combination with McPherson et al. are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 18-34, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the undersigned should he believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

  
James C. Lydon  
Reg. No. 30,082

Atty. Case No.: TUR-127  
100 Daingerfield Road  
Suite 100  
Alexandria, Virginia 22314  
Telephone: (703) 838-0445  
Facsimile: (703) 838-0447